K011410

JUN 2 6 2001

510(k) Summary of Safety and Effectiveness

510(k) Submitter:	Streck Laboratories, Inc. 7002 South 109th Street La Vista, NE 68128
Official Correspondent:	Carol Thompson Quality Assurance/Regulatory Affairs Manager (402) 537-5313
Date Prepared:	May 7, 2001
Names of Device:	
Trade Name:	Para® 5X
Common Name:	Assayed hematology control
Classification Name:	Hematology Quality Control Mixture
Predicate Device:	STaK-Chex (K911582), manufactured by Streck Laboratories, Inc.

Description: Para® 5X is a tri-level multi-parameter hematology control consisting of stabilized human red blood cells, human white blood cells and simulated platelets. The product is packaged in glass vials containing 4.0 ml. The closures are polypropylene screw caps with pierceable liners.

Intended Use: Para 5X is intended for use as a multi-parameter quality control material for ABX Pentra 60 hematology analyzers. It includes assay values for CBC/Diff parameters. It does not include values for the basophil parameter.

Comparison with Predicate Device:

Para 5X is similar to STaK-Chex in composition and use. Both products are multi-parameter hematology controls with wbc differential assays. They both are composed of stabilized human red blood cells, stabilized human wbc and a simulated platelet component. They differ only in the stabilization process employed for preparing the wbc component, in the intended hematology instrument application and Para 5X's inability to provide values for the basophil parameter. STaK-Chex is intended for use on Coulter STKS analyzers and Para 5X for ABX Pentra systems.

The packaging for both contains three control levels that simulate low abnormal, normal and high abnormal CBC values.

Testing Performed:

Four types of studies were conducted to establish performance of Para 5X. a.) Long-term stability (Shelf Life), b.) Open vial stability, c.) Site to Site recovery of values, d.) "With-in Run" precision studies. All testing showed that Para 5X is consistently reproducible and performs within the claims for Shelf Life and Open-Vial stability.

Conclusions Drawn from the Tests:

Para 5X is a safe and effective product useful for controlling the counting procedures of ABC Pentra 5X hematology analyzers. It will perform as claimed when used in accordance with the package insert instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 6 2001

Mr. Paul Kittelson
Quality Assurance/Regulatory Affairs
Streck Laboratories, Inc.
7002 South 109th Street
LaVista, NE 68128

Re: 510(K) Number: K011410
Trade/Device Name: PARA® 5X
Regulation Number: 864.8625
Regulatory Class: II
Product Code: JPK
Dated: May 7, 2001
Received: May 8, 2001

Dear Mr. Kittelson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K001410

Device Name: PARA® 5X

Indications For Use: Para® 5X is intended to be used as a hematology control for complete blood cell count (CBC) and white cell differential (excluding basophil) on ABX Pentra 60 Systems.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011410

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Date: _____